

The opinion in support of the decision being entered today  
was not written for publication and is not binding  
precedent of the Board.

Paper No.13

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

Ex parte Joerg G. Birkmayer

---

Appeal No. 2003-1804  
Application No. 09/896,209

---

ON BRIEF

---

Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER  
and GRON, Administrative Patent Judges.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

This is an appeal under 35 U.S.C. § 134 from an examiner's  
final rejection of Claims 1-33 which are all the claims pending  
in U.S. Application No.09/896,209, filed June 29, 2001.

Introduction

Claims 1-33 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable in view of the combined teachings of Birkmayer (Birkmayer I), U.S. Patent No. 5,712,259, issued on January 27, 1998; Prof. Georg Birkmayer, M.D., Ph.D, NADH The Energizing Coenzyme, Good Health Guide (Keats Publishing, Inc., New Canaan, Connecticut 1998) (Birkmayer II); Langsjoen et al. (Langsjoen), U.S. Patent No. 5,011,858, issued on April 30, 1991; and the website, BioActive Nutrients, "C2 Chromium Picolinate and L-Carnitine," <http://www.bioactivenutrients.com/c2.html>, 1999 (Bioactive Nutrients). Independent Claims 1, 12, and 23 read as follows:

1. A method for alleviating the effects of sleep deprivation in a human being, comprising administering to a human being exhibiting the effects of sleep deprivation an amount of NADH or NADPH or a physiologically compatible salt of NADH or NADPH which is effective to reduce or eliminate said effects of sleep deprivation.

12. A method for alleviating the effects of jet lag in a human being, comprising administering to a human being exhibiting the effects of jet lag an amount of NADH or NADPH or a physiologically compatible salt of NADH or NADPH which is effective to reduce or eliminate said effects of jet lag.

23. A method for enhancing attentiveness or reaction time in a human being, comprising administering to a human being an amount of NADH or NADPH or a physiologically compatible salt of NADH or NADPH which is effective to improve attentiveness or reaction time.

Appeal No. 2003-1804  
Application No. 09/896,209

We have considered the applicant's specification and claims, the applied prior art, and the positions of the examiner and appellant set forth in the examiner's answer and appellant's brief respectively. The examiner also rejected the appellant's claims under 35 U.S.C. § 102, 35 U.S.C. § 103(a), and for double patenting, over Birkmayer I alone. However, we need not reach these rejections because we conclude that the combined prior art teaching establishes the prima facie obviousness under 35 U.S.C. § 103(a) of the invention defined by Claims 1-33. Appellant has presented no objective evidence of nonobviousness. Accordingly, we affirm the examiner's final rejection of all pending claims under 35 U.S.C. § 103(a) in view of the combined prior art teachings.

#### Discussion

"The PTO has the burden under section 103 to establish a prima facie case of obviousness." In re Fine, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Claims 1, 12, and 23 comprise administering to a human being an effective amount of NADH or NADPH or a physiologically acceptable compatible salt of NADH or NADPH. The Claim 1 method is effective for alleviating the effects of sleep deprivation. The Claim 12 method is effective for alleviating the effects of jet lag. The Claim 23 method is effective for enhancing attentiveness or reaction time.

Appeal No. 2003-1804  
Application No. 09/896,209

Applicant's specification describes sleep deprivation as follows (applicant's specification, page 1, lines 17-25):

Sleep deprivation is the condition of being deprived of this needed sleep, resulting in adverse effects on an individual, such as for example, decreased attentiveness, decreased ability to concentrate, decreased reaction time, decreased alertness, and decreased productivity and efficiency. Sleep deprivation can be caused by, for example, sleep disorders, such as insomnia or obstructive sleep apnea, medical illnesses, shifting work schedules, depression, or flying across time zones.

Accordingly, we find that persons with sleep deprivation or jet lag show similar symptoms which both include decreased attentiveness, decreased ability to concentrate, and decreased reaction time. Moreover, we note that appellant states all claims stand or fall together. (Appeal Brief, page 5, Grouping of claims).

The examiner relies on the combined teachings of Birkmayer I, Birkmayer II, Langsjoen, and Bioactive Nutrients as evidence that the claimed inventions would have been obvious to one of ordinary skill in the art at the time the inventions were made. Birkmayer I describes a "method for treating Chronic Fatigue Syndrome(CFS) or alleviating symptoms thereof wherein the reduced form of nicotinamide adenine dinucleotide(NADH) or the reduced form of nicotinamide adenine dinucleotide phosphate(NADPH) or physiologically compatible salts or derivatives of NADH and/or

Appeal No. 2003-1804  
Application No. 09/896,209

NADPH are administered to a person suffering from the syndrome or its symptoms." (Birkmayer I, abstract).

Although Birkmayer I is directed to a method of treating Chronic Fatigue Syndrome (CFS), persons with CFS show similar symptoms to persons with jet lag or sleep deprivation. Birkmayer I teaches that "in patients suffering from Chronic Fatigue Syndrome, a clear alleviation of their symptoms, including but not limited to fatigue, headaches, depression and muscle pain and weakness, is achieved." (Birkmayer I, column 2, lines 43-48). Additionally, in Example II of Birkmayer I, a patient "showed symptoms of fatigue for at least 6 months, sore throat, painful lymph nodes, muscle weakness, muscle pains, headache, short term memory problems, forgetfulness and inability to concentrate." (Birkmayer I, column 7, lines 38-41). After being treated with NADH, the "patient's symptoms were alleviated." (Birkmayer I, column 7, lines 46-48). "The patient reported an improvement in the energy level as reflected by increased exercise programs and shorter lasting fatigue after exercise." (Birkmayer I, column 7, lines 48-50). Thus, symptoms of Chronic Fatigue Syndrome are also common to jet lag and sleep deprivation. Accordingly, it would have been obvious to a person having ordinary skill in the art at the time the invention was made that a prior art method for treating symptoms of Chronic

Appeal No. 2003-1804  
Application No. 09/896,209

Fatigue Syndrome likely would have been effective for treating symptoms of jet lag and/or sleep deprivation.

Moreover, Birkmayer II also suggests applicant's claimed inventions. Birkmayer II teaches that NADH (ENADA) can be administered to improve the energy level and well-being of healthy individuals and individuals with health problems. (Birkmayer II, page 23, fourth paragraph). Birkmayer II states (Birkmayer II, page 23, fourth paragraph):

ENADA is a natural approach to energy, drive and health. ENADA (NADH) energizes both body and brain activity, improves alertness, concentration, emotion, drive, hormone secretion and overall mood enhancement. It helps improve brain cell performance and helps keep cells alive for a longer period of time. The more ENADA (NADH) a cell has available, the more energy it can produce to perform its process efficiently. ENADA (NADH) is available to everyone whose lifestyle demands increased energy, vitality and mental activity.

Birkmayer II discloses that effects observed after administering NADH "included increased oxygen capacity, decreased reaction time and greater mental acuity and alertness." (Birkmayer II, page 25, first paragraph).

Additionally, Birkmayer II teaches that NADH is useful for treating persons suffering from fatigue. Birkmayer II reports recipients stating (Birkmayer II, page 41):

On many mornings, I found it difficult to get up; my body felt heavy and couldn't wake up. It was difficult

Appeal No. 2003-1804  
Application No. 09/896,209

to get through the long hours that I keep to get through my training.... From the first day that I took ENADA, I noticed a difference immediately. I all of the sudden had mental clarity with a sharp state of mind, was able to think clearly, and felt more energetic....My muscles seem to have an endless supply of energy to keep going (I would get very fatigued very quickly before).

Birkmayer II teaches that NADH helps a person wake up, think clearly, and have more energy. Decreased attentiveness, decreased ability to concentrate, and decreased reaction time are common symptoms of sleep deprivation and jet lag. One of ordinary skill in the art at the time the invention was made would have understood from Birkmayer II that administering NADH likely would have been useful for alleviating symptoms of jet lag, alleviating symptoms of sleep deprivation, and enhancing attentiveness or reaction time.

Langsjoen and Bioactive Nutrients teach the use of coenzyme Q10, L-Cartinine or L-glutathion to treat symptoms associated with sleep deprivation, treat symptoms associated with jet lag, or improve attentiveness or reaction time. Langsjoen teaches that Q10 is used to alleviate symptoms of AIDS, such as fatigue and malaise. (Langsjoen, column 3, lines 1-3). Bioactive Nutrients teaches that a deficiency of Cartinine can cause fatigue, muscle weakness, and brain degeneration. (Bioactive Nutrients).

Appeal No. 2003-1804  
Application No. 09/896,209

In our view, persons having ordinary skill in the art would have understood from Birkmayer I and Birkmayer II that NADH would alleviate symptoms related to fatigue, sleep deprivation, and jet lag. One of ordinary skill in the art at the time the invention was made would have understood that Birkmayer II also suggests administering NADH to any person to improve attentiveness and reaction time. Therefore, it would have been prima facie obvious at the time the claimed invention was made to alleviate the effects of sleep deprivation, alleviate the effects of jet lag, and/or enhance attentiveness or reaction time by administering NADH.

Appellant's arguments do not undermine the established prima facie case of obviousness. Appellant argues that Birkmayer I "fails to teach or suggest that the primarily mental symptoms of jet lag and/or sleep deprivation, such as decreased attentiveness or reaction time, could be successfully alleviated by the method disclosed in the Birkmayer '259 patent." (Appeal brief, page 10, second full paragraph). Appellant's argument is unpersuasive. Appellant's claims do not require alleviation and treatment of all effects of sleep deprivation or jet lag. Moreover, Birkmayer I teaches alleviation of symptoms such as inability to concentrate. (Birkmayer I, column 7, lines 38-48).



Appeal No. 2003-1804  
Application No. 09/896,209

Appellant further argues that "neither the Langsjoen patent nor the Bioactive Nutrients website even mention NADH or NADPH, they thus provide no teaching, suggestion nor [sic] motivation for one of ordinary skill in the art to practice the method of the Birkmayer '259 patent to alleviate effects of sleep deprivation and jet lag, or to enhance attentiveness and/or reaction time in an individual." (Appeal Brief, page 10, third full paragraph). Bioactive Nutrients teaches that lack of L-Carnitine causes fatigue. (Bioactive Nutrients). Langsjoen teaches that Q10 is used to alleviate fatigue and malaise. (Langsjoen, column 3, lines 1-3). Birkmayer I and Birkmayer II teach that NADH gives energy and alleviates fatigue. It would have been prima facie obvious to one skilled in the art at the time the invention was made to combine compositions useful for the same purpose to alleviate common symptoms.

Finally, appellant argues that "the enhanced attentiveness was not taught nor [sic] suggested in the prior art, and thus the method of the present invention has lead to 'surprising beneficial results.'" (Appeal Brief, page 11, first paragraph). The record suggests the opposite. Birkmayer II teaches that NADH "energizes both body and brain activity, improves alertness, concentration, emotion, drive, hormone secretion and overall mood enhancement." (Birkmayer II, page 23, fourth paragraph).

Appeal No. 2003-1804  
Application No. 09/896,209

Therefore, improved attentiveness would not have been a  
"surprising beneficial result" to a person having ordinary skill  
in light of the prior art teaching.

Conclusion

For the reasons stated above, we affirm the examiner's final  
rejections of Claims 1-33 of Application No. 09/896,209 under  
35 U.S.C. § 103(a) in view of the combined prior art. We need  
not reach the rejections of appellant's claims over Birkmayer I  
alone.

No time period for taking any subsequent action in  
connection with this appeal may be extended under 37 CFR  
§ 1.136 (a).

AFFIRMED

FRED E. MCKELVEY	)	
Senior Administrative Patent Judge	)	
	)	
	)	
	)	BOARD OF PATENT
RICHARD E. SCHAFER	)	APPEALS AND
Administrative Patent Judge	)	INTERFERENCES
	)	
	)	
	)	
TEDDY S. GRON	)	
Administrative Patent Judge	)	

Appeal No. 2003-1804  
Application No. 09/896,209

KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004